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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,568	JALILI, THUNDER	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for delaying the onset or slowing the progression of hypertension in a subject, does not reasonably provide enablement for prevention of the hypertension by administration of quercetin to a subject for at least seven days prior to the onset of hypertension where the hypertension is not surgically induced or the day of onset of hypertension is not otherwise known. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to the prevention, delaying or slowing the progression of hypertension with quercetin.

The state of the prior art and the predictability or lack thereof in the art:

The prior art, as indicated in the prior art rejections below, disclose the delaying and slowing of the progression of hypertension with quercetin but the prior art does not provide evidence of prevention. Further, the prior art does not provide any disclosure as to how one of ordinary skill in the art would be able to predict the day of on which the onset of hypertension occurs such that one of ordinary skill in the art would administer a nutritional supplement as least seven days prior to day absent surgically inducing the same on a specific day. Further, in a later

study in which the inventor was one of the authors, it was determined that a quercetin supplemented diet did not prevent cardiovascular complications in spontaneously hypertensive rats, i.e. hypertension was not prevented or delayed (Carlstrom et al., Abstract). Carlstrom et al. disclosed that the method of administration was critical to the effectiveness of quercetin in reducing blood pressure, i.e oral gavage was effective in reducing blood pressure but not dietary supplemented quercetin (Carlstrom et al., page 632). Further, Carlstrom et al. disclose that abdominal aortic constriction (AAC) rats only produced local mechanical hindrance as opposed to systemic hypertension (Carlstrom et al., page 632). As such, predictability with respect to prevention of hypertension by administering quercetin at least seven days prior to onset hypertension where hypertension is not surgically induced or the day of onset of hypertension is not otherwise known is low.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification provides examples of delaying and slowing of the progression of hypertension with quercetin but the examples show that hypertension was not prevented (Specification, paragraphs 0069-0072).

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim prevention of hypertension with quercetin, however, Applicant's Specification discloses an example that shows that hypertension was not prevented. The scope of the term "prevention" is such that administration of quercetin will prevent hypertension over the life time of the subject. Further, there is no evidence that one of ordinary skill in the art can predict the day when hypertension will occur. As such, one of ordinary skill in the art would be required to do undue experimentation in order to determine

whether administration of quercetin can prevent hypertension and how one would be able to administer quercetin at least seven days prior to hypertension onset where the hypertension is not surgically induced or the day of onset of hypertension is not otherwise known.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant argues that it has enabled prevention of hypertension. However, contrary to Applicant's arguments, the Specification supports the conclusion that prevention of hypertension is not enabled. SH rats are disclosed to be a model of hypertension resulting from aging with beginning at 5-6 weeks with peak blood pressure at about 12-15 weeks of age (Paragraphs 0066, 0069). As such, in paragraph 0072, the dietary supplement was initiated at 5 weeks and at week 17 there was no difference between control and quercetin treated rats, as such, it can be concluded that the quercetin failed to prevent hypertension. Further, Carlson et al. supports this conclusion as indicated above. Since ACC rats only product local restrictions in blood flow it would appear that they are not sufficiently predictive as to whether quercetin supplementation would prevent hypertension which is borne out by experiments done with spontaneously hypertensive rats.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the Specification as originally filed for the amendment "wherein the nutritional supplement is administered to the subject for at least seven days prior to the onset of hypertension". The Example 1 cited only indicates that on the 8th day after 7 days of

a diet containing quercetin. There is no disclosure citing a range of at least seven days and the only disclosure indicates that the hypertension was surgically induced on the 8th day after the rats were fed for 7 days. As such, there is insufficient evidence to show that the inventor's envisioned the claimed invention at the time the application was filed. See *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (Applicant was not entitled to the benefit of a parent filing date when the claim was directed to a subgenus (a specified range of molecular weight ratios) where the parent application contained a generic disclosure and a specific example that fell within the recited range because the court held that subgenus range was not described in the parent application). See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("[T]he specification does not clearly disclose to the skilled artisan that the inventors... considered the... ratio to be part of their invention.... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion").

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7, 8, 10, 14-16, 27, 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Duarte et al. (2002).

Duarte et al. (2002) expressly disclose that administration of 5 or 10 mg/kg/day quercetin in 1% methylcellulose oral gavage was effective in inhibiting the development of hypertension and reducing left ventricular weight in the L-NAME induced rat model of hypertension and that in L-NAME only rats on the average had systolic pressures of approximately between 120 to 130 mmHg at week 0 of treatment which raised to 160 mmHg on the average at approximately between weeks 4 and 5 of treatment (Abstract, page 1846, Fig. 1).

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duarte et al. (2002), Duarte et al. (2001) in view of Wakat et al. (US Pat. 6,054,128) and Schmitz et al. (US Pat 6,610,320).

Duarte et al. (2002) disclose that administration of 5 or 10 mg/kg/day quercetin in 1% methylcellulose oral gavage was effective in inhibiting the development of hypertension and reducing left ventricular weight in the L-NAME induced rat model of hypertension and that in L-NAME only rats on the average had systolic pressures of approximately between 120 to 130 mmHg at week 0 of treatment which raised to 160 mmHg on the average at approximately between weeks 4 and 5 of treatment (Abstract, page 1846, Fig. 1).

Duarte et al. (2001) disclose oral administration of 10 mg/kg of quercetin in 1% methylcellulose which lowered blood pressure and reduced left ventricular weight compared to controls (Abstract, Pages 118-120).

Wakat discloses the combination of quercetin (preferably about 500 mg) with other nutrients, such as vitamin C and vitamin E and minerals, such as calcium, magnesium copper, manganese, iron, etc., which can be formulated as a consumable liquid, such as juices, or food, which is used to meet a persons cardiovascular system health needs (Column 3, lines 35-68, Columns 4-6, Column 7, lines 1-44).

Schmitz et al. disclose the combination of quercetin with proteins, soluble fibers, rice bran oil, carbohydrates, fats and vitamins and minerals, that the food can be in the form of a cookie and that the food can be used reduce blood pressure (Column 6, lines 38-68, Columns 7-9, Column 10, lines 1-49, Column 13, lines 14-27)

Duarte et al. (2002) disclose that administration of 5 or 10 mg/kg/day quercetin in 1% methylcellulose oral gavage was effective in inhibiting the development of hypertension and reducing left ventricular weight in the L-NAME induced rat model of hypertension and that in L-NAME only rats on the average had systolic pressures of approximately between 120 to 130 mmHg at week 0 of treatment which raised to 160 mmHg on the average at approximately between weeks 4 and 5 of treatment. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination with other vitamins and minerals, the formulation of foods and other beverages or drinks containing the same and parenteral admniistration. However, the prior art amply suggests the same as the prior art discloses the combination of quercetin with other vitamins and minerals, the formulation of the same in beverages, such as juices and foods, such as cookies, that can include proteins, carbohydrates, fats and soluble fibers and parenteral administration As such, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation

that the quercetin nutritional beverages, foods and parenteral administration of quercetin would be effective in lowering blood pressure and reducing left ventricular hypertrophy.

The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
September 23, 2008

/John Pak/
Primary Examiner, Art Unit 1616